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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/602,330 | 06/23/2003 | Clarence Nathaniel Ahlem | 202.2D2 | 9052 |

26551 7590 10/25/2004

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| EXAMINER | |
|---|---|
| BADIO, BARBARA P | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/602,330 | AHLEM ET AL. | |
| | Examiner | Art Unit | |
| | Barbara P. Badio, Ph.D. | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-49 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. The Markush group set forth in the claims contains a plurality of patentably distinct compounds far too numerous to list individually. Due to the numerous variables in the claims, e.g., $R^1$, $R^2$, $R^3$, $R^4$, $R^5$, $R^6$, etc. and their widely divergent meanings, a precise listing of inventive groups cannot be made. For this reason, restriction to one of the following Groups is required under 35 U.S.C. 121, wherein a Group is a set of patentably distinct invention of a broad statutory category, i.e. Composition or Method of Use:

I. Claims 1-25 and 30-43, drawn to various method of use (treating a pathogen infection, an autoimmune disease, inflammation, etc.), classified in 514, various subclasses.

II. Claims 26-29 and 44-49, drawn to compositions, classified in several classes (540, 544, 548, 549 and 552), numerous subclasses.

2. With the election of any one of Group I and II, election of a set of compounds is further required. The following groups are exemplary:

Group I. Claims 1-14, 16-25 and 30-43, drawn to 16α-bromo-3β-hydroxy-5α-androstan-17-one hemihydrate.

Group II. Claims 1-14, 16-25, 30-32 and 34-40, drawn to compounds of formula 1 as defined in claim 1, wherein $R^7$ is $-CHR^{10}-$, $-CHR^{10}-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-CHR^{10}-$; $R^8$ is $-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-$ and $R^9$ is $-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-$.

Group III. Claims 1-9, 15, 16 and 30-40, drawn to compounds of formula 1 as defined in claim 1, wherein $R^7$ is $-CHR^{10}-$, $-CHR^{10}-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-CHR^{10}-$; $R^8$ is $-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-$ and $R^9$ is -O- or $-O-CHR^{10}-$.

Group IV. Claims 1-9, 16, 30-38 and 40, drawn to compounds of formula 1 as defined in claim 1, wherein $R^7$ is $-CHR^{10}-$, $-CHR^{10}-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-CHR^{10}-$; $R^8$ is $-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-$ and $R^9$ is -S- or $-S-CHR^{10}-$.

Group V. Claims 1-9, 15, 16 and 30-40, drawn to compounds of formula 1 as defined in claim 1, wherein $R^7$ is $-CHR^{10}-$, $-CHR^{10}-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-CHR^{10}-$; $R^8$ is $-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-$ and $R^9$ is $-NR^{PR}-$ or $-NR^{PR}-CHR^{10}-$.

Group VI. Claims 1-9, 16 and 30-40, drawn to compounds of formula 1 as defined in claim 1, wherein $R^7$ is $-CHR^{10}-$, $-CHR^{10}-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-CHR^{10}-$; $R^8$ is -O- or $-O-CHR^{10}-$ and $R^9$ is $-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-$.

Group VII. Claims 1-9, 16, 30-37 and 40, drawn to compounds of formula 1 as defined in claim 1, wherein $R^7$ is $-CHR^{10}-$, $-CHR^{10}-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-CHR^{10}-$; $R^8$ is -S- or $-S-CHR^{10}-$ and $R^9$ is $-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-$.

Group VIII. Claims 1-9,16 and 30-40, drawn to compounds of formula 1 as defined in claim 1, wherein $R^7$ is $-CHR^{10}-$, $-CHR^{10}-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-CHR^{10}-$; $R^8$ is $-NR^{PR}-$ or $-NR^{PR}-CHR^{10}-$ and $R^9$ is $-CHR^{10}-$ or $-CHR^{10}-CHR^{10}-$.

3. With the election of Group I, applicant is further required to elect a specific method of use. For example, (a) Method of treating a hepatitis C; (b) Method of treating allergy; (c) Method of treating osteoporosis; (d) Method of treating acute myelitis, etc. Note: With the election of a group of disorders, such as treating a pathogen infection, cancer, precancer, neurological disorder, autoimmune disease, etc., applicant is required to identify a specific condition from under said group.

4. In accordance with the decisions in ***In re Harnisch***, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and ***Ex parte Hozumi***, 3 USPQ2d 1059 (bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. 103.

5. Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species from under the elected Group for search purposes, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.

6. The above list in #2 is not exhausted as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, if desired, upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group of compounds that are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

7. Applicant is reminded that upon cancellation of claims to non-elected invention, the inventors must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.17(i).

**8. Rationale Establishing Patentable Distinctiveness Within Each Group**

Each Invention Set listed above is directed to compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over either of the other inventions, i.e. they are patentable over each other. Chemical structures that are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

**The above Groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:**

Groups I and II are related as process of use and product. The inventions can be shown to be distinct if either or both of the following can be shown: (a) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using ht e product (MPEP 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product as demonstrated throughout the present specification and in claims 1, 16 and 18-25 which are directed to several different methods of using the products, for example treating allergy and treating osteoporosis.

Each of the different methods of use inventions set forth in Group I is unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Method of use are unrelated if one of three differences are found between them. These differences are 1) the population being treated, 2) the material being used, and 3) the methodology of treatment. If any one or more of these differences exist and are patentably distinct, then the methods are unrelated. In the instant case, the different methods of use inventions are unrelated because the patient population treated for each method is divergent. For example, a method of treating allergy presumes that the patients being treated has allergy while a method of treating osteoporosis presumes the patient has osteoporosis.

In addition, because of the plethora of classes and/or subclasses in which the claimed compounds fall, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. ***Advisory of Rejoinder***

The following is a recitation of M.P.E.P. §821.04, Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
>
> Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined . If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR

> 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.
>
> In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

***Telephone Inquiry***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
October 19, 2004